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BioCore Medical Technologies, Inc.

State-of-the-Art Biomaterials Technologists

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Silver Spring, Maryland 20904
U.S.A.

510(k) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92"

"The assigned 510(k) number is: K012995

Submitter's Name and Address:

BioCore Medical Technologies, Inc.
11800 Tech Rd. Suite 240
Silver Spring, MD 20904

Contact Person, Telephone and Fax Number:

Ajay Kumar, VP of Operations
Phone: (301) 625-6818
Fax: (301) 625-6819

Date the Summary was Prepared:

September 19, 2001

Device Names:

Proprietary Name:	Collatek® Sheet
Model number:	xxxxxxx
Common Name:	hydrocolloid wound sheet
Classification Name:	occlusive, wound and burn dressing

Predicate Device:

Trade name:	Cutinova® hydro
Company:	Beirsderf , Inc.
Trade name:	DuoDerm® Extra Thin
Company:	Convatec™, A Bristol-Myers Squibb Co.

Kollagen™

Device Description:

Collatek® Sheet is a sterile, disposable, single use, wound-dressing device for the management of dermal lesions and injuries. Collatek® Sheet is packaged as a self-adhering island dressing which is able to conform to most wound sites. Collatek® Sheet consist of a hydrocolloid sheet with a clear adherent medical tape backing on one side and a peel-off silica-coated paper on the other. It is to be used manage full and partial thickness wounds with light exudate.

Basis for Substantial Equivalence:

1. Indications for Use

Collatek® Sheet will be used to manage full thickness and partial thickness wounds with light exudate. Collatek® Sheet is intended for use on these types of wounds: pressure ulcers (stages I-IV), venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first and second degree burns, donor sites and other bleeding or secreting dermal lesions/injuries.

Collatek® Sheet's intended use is analogous to the commercially available predicate devices (Cutinova® hydro and DuoDerm® CGF).

2. Instructions for Use

Collatek® Sheet's manner of application is similar to other wound care products. First, cleanse and dry the wound the wound. Second, apply medication to wound as indicated. Third, apply Collatek® Sheet to the wound surface, smooth and secure the self-adhesive border. Lastly, change dressing as needed in accordance with labeling instructions.

Collatek® Sheet's indications for use are similar to those of commercially available predicate devices (Cutinova® hydro and DuoDerm® CGF).

3. Technological Characteristics

Collatek® Sheet is a hydrocolloid wound dressing. Collatek® Sheet protects the wound bed and newly formed granulation tissue by formation of an occlusive gelatinous barrier

Collatek® Sheet is packaged as a low moisture hydrocolloid product, this gives Collatek® Sheet the advantage of being able to absorb liquid exudate and the flexibility to conform to most wound sites. Collatek® Sheet is designed for use on a lightly exudating wound with simple or complex wound irregularities.

Collatek® Sheet is comparable in design and function to the commercially available predicate devices (Cutinova® hydro and DuoDerm® CGF).

4. Materials

Collatek® Sheet's main constituents are: gelatin, glycerin and collagen, pectin and guar gum. Collatek® Sheet's collagen is a fibrous Type I bovine collagen. The constituents of Collatek® Sheet are similar to the constituents of the commercially available predicate devices (Cutinova® hydro and DuoDerm® CGF).

5. Performance

Bench testing was performed to verify that the performance characteristics of Collatek® Sheet are comparable to the currently marketed predicate device. Collatek® Sheet is designed to absorb light amounts of exudates while forming a protective gelatinous barrier. The collagen helps to protects the wound bed and newly formed granulation tissue by formation of an occlusive gelatinous barrier that is conducive to wound healing.

6. Safety

Biocompatibility testing has confirmed that Collatek® Sheet meets requirement as stated in the FDA Blue Book Memorandum G95-1 and in ISO10993. Biocompatibility tests were performed by North American Science Associates, Inc. (NAmSA) in accordance with GLP. Biocompatibility data has shown that Collatek® Sheet is safe for

use as a medical device for wound care management and is substantially equivalent to the commercially available predicate devices (Cutinova® hydro and DuoDerm® CGF).

7. Sterility and Packaging

Collatek® Sheet will be packaged in a single use, disposable silica-coated polyethylene pouch. The package and its contents will be sterilized using electron beam radiation. Collatek® Sheet will be sterilized to an SAL value of 10^{-6}. The sterilization process will be validated using ANSI/AAMI/ISO1137 guidelines.

Conclusion

Collatek® Sheet is equivalent in design, function, materials and intended use and is therefore substantially equivalent to the commercially available predicate devices: (Cutinova® hydro and DuoDerm® CGF). We therefore submit that Collatek® Sheet is substantially equivalent to the predicates hyCURE® sheet and DuoDerm® CGF.

Table I-2.1 provides a side-by-side comparison for a basis of substantial equivalence for Collatek® Sheet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2001

Mr. Ajay Kumar
Vice President of Operations
BioCore Medical Technologies, Inc.
11800 Tech Road
Suite #240
Silver Springs, Maryland 20904

Re: K012995
Trade Name: Collatek® Sheet
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 6, 2001
Received: September 6, 2001

Dear Mr. Kumar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012995

Device Name: Collatek Sheet

Indications for Use:

Collatek Sheet may be used in the management of:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2nd degree burns
- Cuts, abrasions and surgical wounds

Contraindications:

Collatek Sheet should not be used on persons sensitive to bovine products.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012995

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)